THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SOMAXON PHARMACEUTICALS, INC., and PROCOM ONE, INC.,	)	
Plaintiffs	)	
v.	)	Civ. No. 11-107-SLR
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Counterclaim-Plaintiffs	)	
v.	)	
SOMAXON PHARMACEUTICALS, INC., PROCOM ONE, INC., and J. RETTERMAIER & SOHNE GMBH + CO. KG,	)	
Counterclaim-Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 28th day of July, 2011, having considered defendant's motion to dismiss or, in the alternative, for a more definite statement, and the papers filed in connection therewith;

IT IS ORDERED that said motion (D.I. 15) is granted, as follows.

1. **Background**.[1] Somaxon Pharmaceuticals, Inc. ("Somaxon"), ProCom One, Inc. ("ProCom") (collectively "plaintiffs") and J. Rettenmaier & Sohne GMBH + Co. KG

[1]The court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). (D.I. 1 at ¶ 7)

("JRS" or "counterclaim-defendant")[2] filed suit alleging that Par Pharmaceutical Inc. and Par Pharmaceutical Companies, Inc.'s (collectively "Par" and "defendants") Abbreviated New Drug Application ("ANDA") to market a generic version of a Somaxon drug infringed upon one of Somaxon's patents. (D.I. 16 at 1) Par replied by seeking declaratory judgment of invalidity and non-infringement of the named patent, and an additional six unasserted patents. (*Id.*) Somaxon and JRS gave Par covenants not to sue for the six unasserted patents identified in counts III through XIV of Par's counterclaim, and now move for an order to dismiss counts III through XIV of Par's counterclaims pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. (D.I. 15; D.I. 16 at 1)

2. Somaxon[3] produces a Food and Drug Administration (the "FDA") approved doxepin hydrochloride drug product, branded as Silenor®, for the treatment of insomnia. (D.I. 1 at ¶ 11) Pursuant to 21 U.S.C. § 355(b)(1), Somaxon listed eight patents covering Silenor® in the FDA Orange Book.[4] (D.I. 16 at 2) Those patents include: U.S. Patent No. 5,502,047 ("the '047 patent"); U.S. Patent No. 6,211,229 ("the '229 patent"), and six other patents, referred to hereinafter as the "Unasserted

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[2]Collectively, Somaxon, ProCom and JRS will be referred to as "plaintiffs and counterclaim-defendant."

[3]Somaxon is incorporated in the State of Delaware, and has a principal place of business in San Diego, California. (D.I. 1 at ¶ 1)

[4]Somaxon added a ninth patent to the Orange Book for Silenor®, but that patent is not at issue in this case. (D.I. 16 at 2 n.2)

Patents."[5] (*Id.*) The '047 and '229 patents[6] are owned by ProCom,[7] and exclusively licensed to Somaxon. (D.I. 1 at ¶12) JRS[8] owns the Unasserted Patents, and has licensed them to Somaxon. (D.I. 16 at 2)

3. Par[9] is interested in producing a generic version of Silenor® and was the third filer of an ANDA for approval to manufacture and market a generic verison of Silenor®. (D.I. 20 at 8) The first and second filers were Actavis Elizabeth LLC ("Actavis") and Mylan Pharmaceuticals, Inc. ("Mylan"). (*Id.*) Actavis and Mylan notified Somaxon that they had filed ANDAs for a generic version of Silenor® on the same day, November 2, 2010, entitling them to share the 180-day exclusivity period that prohibits other generic manufacturers from entering the market pursuant to 21 U.S.C. § 355(j)(5)(D). (*Id.*) Somaxon filed a patent infringement suit against Actavis and Mylan on December 15, 2010. (D.I. 16 at 3)

4. On December 21, 2010, Par notified plaintiffs and counterclaim-defendant

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[5]The six Unasserted Patents are: U.S. Patent Nos. 5,585,115; 5,725,884; 5,866,166; 5,948,438; 6,103,219; 6,217,909. (D.I. 16 at 1 n.1)

[6]The '047 patent is due to expire on March 26, 2013, and the '229 patent is due to expire on February 17, 2020. (D.I. 16 at 2 n.3, 3)

[7]Procom is incorporated in the State of Texas, and has a principal place of business in Steamboat Springs, Colorado. (D.I. 1 at ¶ 2)

[8] JRS is incorporated in Germany and has a principal place of business in Rosenberg, Germany. (D.I. 9 at ¶ 7 under Counterclaims)

[9]Par Pharmaceuticals, Inc. is incorporated in the State of Delaware and has a principal place of business in Spring Valley, New York. (D.I. 1 at ¶ 3) Its parent company, Par Pharmaceutical Companies, Inc., is incorporated in the State of Delaware and has a principal place of business in Woodcliff Lake, New Jersey. (D.I. 1 at ¶ 4)

that it had submitted ANDA No. 202510 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of 3 mg and 6 mg doxepin hydrochloride tablet generic of Somaxon's Silenor® drug before the expiration of the '229 patent. (D.I. 1 at ¶ 14) Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), Par also notified Somaxon and ProCom that the ANDA contained a paragraph III certification of the '047 patent[10] as well as paragraph IV certifications for the '229 patent and the Unasserted Patents listed in the Orange Book for Silenor® alleging that of all these patents were invalid, unenforceable, or not infringed by Par's generic product. (D.I. 16 at 3)

5. On February 2, 2011, plaintiffs filed a patent infringement action asserting the '229 patent, but not the Unasserted Patents. (*Id.* at 4) Par responded on February 23, 2011, seeking declaratory judgments of invalidity and non-infringement of the '229 patent in addition to the Unasserted Patents. (*Id.*) Somaxon and JRS provided Par with covenants not to sue for the Unasserted Patents and requested that Par dismiss its declaratory judgment counterclaims against those patents. (*See Id.*, ex. A, Letter from D. Manspierzer to D. Brown)

6. On April 18, 2011, plaintiffs and counterclaim-defendant brought the present motion to dismiss alleging that, by presenting Par with covenants not to sue, there is no case or controversy as to those patents, and that counts III through XIV addressing those patents in Par's counterclaims should be dismissed for lack of subject matter

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[10]The paragraph III certification by Par indicates Par believes the '047 patent is valid and that its ANDA should not be approved by the FDA until the '047 patent's expiration date.

jurisdiction. (D.I. 20 at 2; D.I. 16 at 2)

7. **Legal Standard**. Not only may the lack of subject matter jurisdiction be raised at any time, it cannot be waived and the court is obliged to address the issue on its own motion. *See Moodie v. Fed. Reserve Bank of NY*, 58 F.3d 879, 882 (2d Cir. 1995). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000).

8. Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *See* 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed. 1997). Under a facial challenge to jurisdiction, the court must accept as true the allegations contained in the complaint. *See id.* Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

9. Under a factual attack, however, the court is not "confine[d] to allegations in the . . . complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *see also Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977). In such a situation, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court

from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891). Although the court should determine subject matter jurisdiction at the outset of a case, "the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation." 2 Moore § 12.30[1]. Rather, a party may first establish jurisdiction "by means of a nonfrivolous assertion of jurisdictional elements and any litigation of a contested subject-matter jurisdictional fact issue occurs in comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection)." *Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co.*, 513 U.S. 527, 537-38 (1995) (citations omitted).

10. **Discussion**. "[A] covenant not to sue divests the court of declaratory judgment jurisdiction vis-a-vis those claims [which the covenant addresses]." *Boston Scientific Corp. v. Johnson & Johnson Inc.*, 679 F. Supp. 2d 539, 544 n.5 (D. Del. 2010); s*ee Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054,1060 (Fed. Cir. 1995). In the case at bar, the covenants not to sue address the Unasserted Patents in their entirety. There is no case or controversy regarding those patents because the covenant not to sue removes the original subject matter jurisdiction of this court. Par's ability to market generic Silenor® based on the potential that Somaxon or JRS may bring suit regarding these patents in the future is a non-issue.

11. **Conclusion**. For the aforementioned reasons, the court grants plaintiffs and counterclaim-defendant's motion to dismiss for lack of subject matter jurisdiction.

United States District Judge